USP 800
Provider
What is USP <800>?

• The United States Pharmacopeia (USP) is a nonprofit organization that sets standards for quality and safety of medications.

• Chapter <800> specifically outlines how healthcare organizations need to handle hazardous drugs (HDs) to reduce unintentional exposure.
  – The standards apply to all personnel who work in healthcare organizations

• These standards are enforceable by The Joint Commission and CMS.
Hazardous Drugs (HD) are defined by NIOSH (National Institute for Occupational Safety and Health) as having one or more of the following characteristics:

- Carcinogenicity (Risk for causing cancer)
- Teratogenicity (Risk for causing birth defects)
- Reproductive toxicity for both males and females (Risk for difficulty getting pregnant or staying pregnant)
- Organ toxicity at low doses
- Genotoxicity (Risk for causing genetic mutations)
WHAT ARE THE POTENTIAL RISKS?
Acute and long term effects

- Hair Loss
- Cardiac Toxicity
- Kidney Damage
- Hearing Loss
- Nausea
- Rashes

Healthcare Worker

Cancer
Infertility
Reproductive Outcomes
Why is this important?

The Focus is on Healthcare Worker Safety!
How can exposure occur?

- Exposure can occur when hazardous drugs are inhaled, touched, injected or ingested OR if body fluids are splashed or spilled.

- Contamination could be on:
  - Packages containing hazardous drugs
  - The outside of prepared medications
  - Counters or tables
  - Any number of other containers or surfaces
How can exposure occur?

- Every aspect of handling hazardous drugs may result in exposure if proper precautions are not taken.
Exposure Routes

• Absorption through skin and/or mucous membranes
  – Includes coming in contact with hazardous drug OR body fluids
• Inhalation if drugs or body fluids spray into the air
• Injection through a needle stick containing HD or blood
• Ingestion through eating contaminated food or touching contaminated hands to skin or mucous membranes
If I don’t work in a patient care area, why do I need to know about this?

There is a risk for being exposed outside of patient care areas. The following are all examples of potential exposures:

1. A patient who received hazardous drugs is in the cafeteria for lunch and throws up
2. A patient is in the elevator and their IV tubing containing hazardous drug comes apart and spills
3. A box containing hazardous drug starts leaking as it is transported through the hospital
More exposure examples for staff in patient care areas

• Pharmacy personnel and nurses:
  – HDs could be splashed, spilled or injected during drug preparation and administration

• EVS and patient care staff:
  – Removing linens from a patient’s room
  – Removing trash from the pharmacy or patient care unit
  – Handling body fluids
How do I protect myself against exposure?

1. Minimize the risk for exposure by adhering to policies and Standard Operating Procedures (SOPs)
2. Utilize Personal Protective Equipment (PPE) when indicated
3. Utilize other safety devices available in the pharmacy and to nursing when administering medications
Is it Hazardous?

• If you encounter some type of spill, consider it hazardous until otherwise identified.

• If you have been exposed, call Employee Health (during business hours) and the nursing House Supervisor (after hours) for further direction.
  – More details on exposure can be found in the HD SOP

• Complete an [Eye on Safety](#) and notify your supervisor.
There is a “Hazardous Drug Resources” page on My Children’s intranet.

Located on the My Children’s home screen on the right hand side.

Medications that are on the Hazardous Drug List can be found here.
What will I find on the HD Resources Page?

1. Hazardous Medication List
   1. Each HD in the organization and it’s risk category

2. Safety Data Sheet (SDS) link
   1. All hazardous drugs have a SDS that is helpful if there is a spill or exposure

3. Other USP <800> Resources
Resources in PolicyStat

Policies:

• ADM244 Hazardous Drug Handling, includes Standard Operating Procedures
• Med5h Hazardous Drugs: Administration, Handling and Disposal
• Med9h Medication Administration

Additional policies related to specific departments and HDs also available on PolicyStat
Basic HD Spill Control

• All personnel who might be required to clean up a spill must receive proper training in spill management and the use of personal protective equipment (PPE) and N95 masks.
Basic HD Spill Control

Those staff that have not been trained in hazardous drug spill clean up should: **SWIM**

- **Stop** the Spread. Cover the spill if possible
- **Warn** others and call for assistance
  - Call 402-955-8999 to notify the Safety Officer for direction and coordination of the spill cleanup.
  - Notify the House Supervisor of the location of the spill
- **Isolate** the area.
- **Mitigate** risk and minimize exposure by donning full PPE and keeping others away
If I encounter a spill, what should I do?

• Call the call center at x8999 and follow “SWIM”
• Wipe it up
• Ignore it and keep walking
• Call the Ghostbusters
If I have a question about USP<800>, what are my appropriate resources?

a. PolicyStat
b. Google search
c. My supervisor
d. HD Resource Page on Intranet
e. A, C, and D
What do I do if I think I was exposed to a Hazardous Drug?

a. Call Employee Health (if during business hours)
b. Contact the nursing House Supervisor (if after hours)
c. Call the IT Helpdesk
d. Ignore it
e. A and B
This next set of USP<800> related education will review in more detail information that is pertinent for Providers.
Why are drugs other than antineoplastics (chemo agents) included on the NIOSH list?

- Drugs other than antineoplastics are included on the NIOSH list because they meet the definition of a HD.
- It’s not only carcinogens that are included; there are also teratogenic or developmental toxins, reproductive toxins, organotoxins, or genotoxins.
What do the different risk categories mean?

- HDs are grouped in the different categories based on drug make-up and the amount of manipulation required.
- You may see different routes of the same drug in different categories due to amount of manipulation.
- PPE needs also vary based on the category.
HD Classifications

• Each Hazardous drug in the organization has been classified into 3 categories
• Each risk category is color coded
• Each HD will have a risk indication in the Medication Administration Record (MAR) and on the drug label
• Each HD will be delivered from pharmacy in an HD bag
## What Medications Are Included?

### Minimal Risk HD
- Primarily medications which NIOSH identify as having potential reproductive risks
- Examples: Topiramate PO, Clonazepam PO, Fluconazole PO & Warfarin PO

### Moderate Risk HD
- Oral chemo, immunosuppressants
- Other oral medications on the NIOSH list
- Examples: PO Cyclosporine, PO Azathioprine, Mercaptopurine oral solution, Methotrexate tablet

### High Risk HD
- Injectable chemotherapies
- Other injectable medications on the NIOSH list
- Examples: IV Methotrexate, IV Ganciclovir
Minimal Risk HDs in the MAR and label

HAZARDOUS DRUG - MINIMAL RISK

Ordered Admin
Amount: 1 tab (1 × 1 mg tab)

Moderate risk HDs and High Risk HDs have similar indications in the MAR and on the label
Moderate Risk HDs in the MAR and label
High Risk HDs in the MAR and label
Antineoplastic Indicators

[Image of a label with the text: DACTINomycin (COSMEGEN) 0.5 mg/mL push injection 0.445 mg. The label indicates that it is a hazardous drug - high risk and must NOT be filtered. For IV use ONLY.]

Ordered Admin Amount: 0.445 mg = 0.89 mL of 0.5 mg/mL

[Image of a prescription with the text: DOSEEDGE, TWO
ORD#: 298994
DACTINomycin (COSMEGEN) 0.5 mg/mL push injection 0.445 mg
0.445 mg = 0.89 mL of 0.5 mg/mL
Route: IV Frequency: ONCE
Due: 10/7/19 1045
ANTINEOPLASTIC
Must NOT filter.
Action: FD REPRINT]
Inpatient Signage on Doors

• All patients receiving HDs should have a sign outside their hospital room.

• The signs help to identify that the patient may need different PPE for handling of blood and body fluids.

• Sign in Hubbard Units:
  
  HAZARDOUS MEDICATION
Door Signs in Wiebe Units:

HAZARDOUS MEDICATION PRECAUTIONS
Minimal Risk PPE guide

<table>
<thead>
<tr>
<th>Hazardous Drug Administration:</th>
<th>Gloves</th>
<th>Chemo Gown</th>
<th>Mask/Goggles or Face Shield</th>
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<tbody>
<tr>
<td>Single / Wear Double Gloves</td>
<td>If risk of splash</td>
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Managing Blood/Body Fluids:

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HAZARDOUS MEDICATION PRECAUTIONS
Moderate / High Risk PPE guide

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Acknowledgement form

Why do I need to sign an acknowledgement of risk form?

• USP 800 requires in writing that healthcare personnel acknowledge they understand the risks of hazardous medications as it pertains to their job role in the organization.

• Because we are a healthcare facility, any employee could be exposed unknowingly, thus we need to inform all employees of these risks.
  – This form documents that the staff member is aware of the risks with handling HD
References

- USP General Chapter <800> Hazardous Drugs Handling in Healthcare
- NIOSH List of Antineoplastic and Other Hazardous Drugs in Healthcare Settings
- APHON Chemotherapy and Biotherapy Curriculum
- BD JCR Improving Safe Handling Practices for Hazardous Drugs
- ONS Safe Handling of Hazardous Drugs
- ASHP The Chapter<800> Answer Book